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December 12, 2024

The Honorable Jennifer L. Hall
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.,
C.A. No. 21-1015-JLH

Dear Judge Hall:

We write on behalf of Sarepta concerning the Court's Order of yesterday evening, and in particular, the Court's suggestion concerning bifurcation of next week's trial (D.I. 669 at 4). Sarepta fully supports the idea of bifurcation, and offers the following thoughts to the extent they are helpful to the Court's consideration of the issue.

Sarepta proposes that validity and willfulness be tried in the first phase of trial next week, and that all witnesses other than the damages experts testify in Phase 1 (since numerous witnesses address subject matter touching on both liability/willfulness and damages). Sarepta expects that the issues of validity and willfulness would go to the jury on Thursday.

The jury verdict on liability presents four possible outcomes: **Scenario 1:** The jury finds both parties' patents invalid. In this case, there will be no need for a damages trial, and the jury can be excused. **Scenario 2:** The jury finds Sarepta's patent valid and NS's patent invalid. In this case, the same jury would proceed immediately to damages, but it would be a shorter presentation because the jury would only need to hear Sarepta's damages claim. **Scenario 3:** The jury finds NS's patent valid and Sarepta's patent invalid. Here, the jury would only need to resolve NS's damages claim, and NS's separate challenge to Sarepta's eligible lost profits period would be moot. **Scenario 4:** The jury finds both parties' patents valid. In this case, Sarepta would propose that the Court excuse the jury, take cross-motions for summary judgment on the propriety of lost profits, and then the parties could appeal both liability and the lost profits ruling (since the case would be immediately appealable under 28 U.S.C. 1292(c)(2)). If the Federal Circuit reverses validity on both patents, the case will be over. If it affirms one and reverses the other, the prevailing party's damages claim can be tried on remand (if the case does not settle at that point). And if the Federal Circuit affirms both liability verdicts, the Federal Circuit will also rule on the summary

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judgment motion, clarifying whether the parties are eligible to recover lost profits, and the case will proceed on remand accordingly.¹

In short, in three of the four possible scenarios, next week's trial will be shortened, either because there will be no damages phase at all or because there will be a one-way damages trial, and in the fourth, the Court and the parties would have the benefit of the Federal Circuit's decision before proceeding. Sarepta respectfully submits that this approach would be the most efficient use of the Court's and the parties' resources.

Respectfully,

/s/ Rodger D. Smith II

Rodger D. Smith II

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via CM/ECF and e-mail)

¹ Sarepta is not aware of any cases where this issue has arisen in a situation like this where both parties are asserted competing patents and lost profits claims in the same trial. There is one district court case where the issue arose at the summary judgment stage involving a lost profits claim where plaintiff's product had been found to infringe in a different case that was on appeal. *See Medtronic Vascular Inc. v. Abbott Cardiovascular Sys., Inc.*, 2009 WL 1421632, at *4 (N.D. Cal. May 15, 2009). That case is, of course, non-binding. It also involved a fundamentally different scenario because the infringement finding was in a different case that was already on appeal, and in which no damages trial had yet been held, so damages could be offset in the last damages trial to occur.